K110775
p1/3

MAY 13 2011

Section III 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: _____

1. Date of Submission: February, 15, 2011

2. Sponsor
   CONTEC MEDICAL SYSTEMS CO., LTD
   NO.24 Huanghe West Road, Economic &Technical Development Zone,
   Qinhuangdao, Hebei Province, 066004,China
   Establishment Registration Number: 3006979678
   Contact Person: Xueyong Li
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3. Submission Correspondent
   Ms. Diana Hong & Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023, Shanghai, 200237, China
   Tel: +86-21-22815850
   Fax: 240-238-7587
   Email: info@mid-link.net

4. Proposed Device Identification

   Proposed Device Name: Electronic Sphygmomanometer
   Proposed Device Model: CONTEC08C
   Classification: Class II
   Product Code: DXN
   Regulation Number: 21 CFR 870.1130
   Review Panel: Cardiovascular
   Intended Use Statement:

   CONTEC08C Electronic Sphygmomanometer is intended to measure the systolic, diastolic and mean blood pressure as well as pulse rate via non-invasive oscillometric technique in which an inflatable

cuff is wrapped around the upper arm. It can be used on adult individuals.

5. Predicate Device Identification

510(k) Number: K093013
Product Name: Blood Pressure Monitor, MD200A
Manufacturer: Beijing Choice Electronic Technology Co., Ltd

6. Device Description

The proposed device, CONTEC08C Electronic Sphygmomanometer is battery driven automatic non-invasive Blood Pressure Monitor. The device can automatically complete the inflation, deflation and BP measurement, which can measure systolic, diastolic and mean blood pressure as well as the pulse rate at upper arm within its claimed range and accuracy via the oscillometric technique. User can select the unit of the measurement: mmHg or kPa. It can be only used on adult individuals.

The device has the data storage function for data review including measurement time, systolic blood pressure, diastolic blood pressure, mean blood pressure and pulse rate. These records can be uploaded to PC via USB and processed with the PC software.

The device has technical alarm function which will be triggered when the battery voltage is lower than 3.7V, and this alarm can not be cancelled unless being closed or the power replaced.

7. Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1: 1988 +A1: 1991 +A2: 1995, Medical Electrical Equipment – Part 1: General requirements for safety.

IEC 60601-1-2: 2007, Medical Electrical Equipment – Part 1: General requirements for safety-2, Collateral Standard: Electromagnetic compatibility – Requirements and tests.

ANSI/AAMI SP10: 2002 & A1: 2003 & A2: 2006, Manual, electronic, or automated sphygmomanometers

8. Substantially Equivalent Conclusion

The proposed device, CONTEC08C Electronic Sphygmomanometer, is determined to be

Substantially Equivalent (SE) to the predicate device, Blood Pressure Monitor MD200A (K093013), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Contec Medical Systems Co., Ltd.
c/o Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 237-023
Shanghai 200237
CHINA

MAY 13 2011

Re: K110775
Trade/Device Name: Electronic Sphygmomanometer, CONTEC08C
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: March 18, 2011
Received: March 21, 2011

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110775

Section II Indications for Use

510(k) Number: K110775
Device Name: Electronic Sphygmomanometer, CONTEC08C

Indications for Use:

CONTEC08C Electronic Sphygmomanometer is intended to measure the systolic, diastolic and mean blood pressure as well as pulse rate via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm. It can be used on adult individuals.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110775